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| APPLICATION NO.   | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO.        |  |
|---|-----------------|----------------------|------------------------|-------------------------|--|
| 09/824,905  | 04/02/2001      | Sharat Singh         | 0225-0033.22           | 2421                    |  |
| 33603   | 7590 01/08/2004 |                      | EXAM                   | EXAMINER                |  |
| ACLARA BIOSCIENCES, INC. 1288 PEAR AVENUE MOUNTAIN VIEW, CA 94043 |                 | TUNG, JOYCE          |                        |                         |  |
|   |                 |                      | ART UNIT               | PAPER NUMBER            |  |
|   |                 |                      | 1637                   | 24                      |  |
| ·   |                 |                      | DATE MAILED: 01/08/200 | DATE MAILED: 01/08/2004 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)                           |  |  |  |
|---|---|--|--|--|--|
| Advisory Action   | 09/824,905  | SINGH ET AL.                           |  |  |  |
| Advisory Action   | Examiner  | Art Unit                               |  |  |  |
|   | Joyce Tung  | 1637                                   |  |  |  |
| The MAILING DATE of this communication appe   | ars on the cover sheet with the c                                       | orrespondence address                  |  |  |  |
| THE REPLY FILED 7/1/2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.  |   |  |  |  |  |
| PERIOD FOR REPLY [check either a) or b)]  |   |  |  |  |  |
| a) The period for reply expires <u>3</u> months from the mailing date of the final rejection.   |   |  |  |  |  |
| b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).  Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if imely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |  |  |  |  |
| 1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  |   |  |  |  |  |
| 2. The proposed amendment(s) will not be entered because:   |   |  |  |  |  |
| (a) Methey raise new issues that would require further consideration and/or search (see NOTE below);  |   |  |  |  |  |
| (b) ☐ they raise the issue of new matter (see Note below);  |   |  |  |  |  |
| (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  |   |  |  |  |  |
| (d) They present additional claims without canceling a corresponding number of finally rejected claims.   |   |  |  |  |  |
| NOTE: please see the attgched.  |   |  |  |  |  |
| 3. Applicant's reply has overcome the following rejection   | ion(s):   |  |  |  |  |
| 4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).   |   |  |  |  |  |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see the attached.  |   |  |  |  |  |
| 6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection.   | ause it is not directed SOLELY to                                       | o issues which were newly              |  |  |  |
| 7. For purposes of Appeal, the proposed amendment<br>explanation of how the new or amended claims wo  | (s) a)⊠ will not be entered or b)<br>ould be rejected is provided belov | ☐ will be entered and an wor appended. |  |  |  |
| The status of the claim(s) is (or will be) as follows:  |   |  |  |  |  |
| Claim(s) allowed:  Claim(s) objected to:  Claim(s) rejected: <u>claims 11-24</u> .  Claim(s) withdrawn from consideration:  |   |  |  |  |  |
| . ☐ The drawing correction filed on is a) ☐ approved or b) ☐ disapproved by the Examiner.   |   |  |  |  |  |
| P. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s)   |   |  |  |  |  |
| 0. ☐ Other:   |   |  |  |  |  |
|   |   |  |  |  |  |
|   |   |  |  |  |  |

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1. The newly added language "the e-tag receptor having a charge" and the capture agent "that has a charge opposite to that of e-tag reporters so that" in claim 1 raise new issue that would require further consideration and/or search.

2. The newly amended language would not overcome the rejection of Claims 11-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (5,470,705) in view of Babon et al. (5,851,770) because Grossman discloses the probe used in the method of detecting a plurality of different sequences in a target sequence has the features of the e-tag probe. For example, the probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The teachings suggest that the probe of Grossman has a charge. While the instant claims claim (D,M)-N which is an e-tag reporter in which D is a detection group, M is mobility modifier and N is a nucleotide. Thus, the teachings of Grossman et al. read on the limitations of the claims.

The response filed 9/12/2003 argues that Babon is no longer applicable, as the use of the capture agent in the instant invention to create differential between undigested probe ad released e-tag reporters is different from the wash step disclosed by Babon. However, the intended use as discussed in the response can not make the patentable distinction between two products. Based upon the teachings of Grossman and Babon et al. set forth in section 3 of the Office action mailed 7/1/2003, the teachings of Grossman and Babon et al. read on the limitations of the claims. Thus the rejection is maintained.

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3. Claim 24 also remains rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705 (1995)) in view of Babon et al. (5,851,770 (1998)) as applied to claims 11-18 above, and further in view of Ullman et al. (6,251,581B1 (2001))

The teachings and suggestions of Grossman et al. and Babon et al. are discussed previously.

Grossman et al. and Babon et al. do not disclose the detectable labels which are the compounds listed in claim 24.

Ullman et al. disclose a method for determining an analyte in a medium (See the Abstract). The method applies a chemiluminescent compound associated with an specific binding pair member (See column 4, lines 54-65 and column 5, lines 8-14). The compound has the same structure as the compound listed in claims 29 (See column 42-58).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply the chemiluminescent compound of Ullman et al. to the probe of Grossman et al in order to construct a set of electrophoretic tag probe. Ullman et al. disclose a chemiluminescent compound to bind to a specific binding pair complex so that the detection may be performed without heating the medium to produce light and conducted at a constant temperature (See column 7, lines 28-31). By avoiding heating, protein analytes would not be inactivated and thus the sensitivity of the method is increased. It would have been <u>prima facie</u> obvious to apply the fluorescent molecules to the electrophoretic release tag to construct the set of electrophoretic tag probe to avoid inactivating protein analytes.

The response argues that the composition of the instant invention comprises pluralities of such compounds that form distinct peaks in an electropherogram upon electrophoretic

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separation. However, these compounds are not attached to the e-tag reporter in claim 11.

Therefore Applicant's arguments filed 9/12/2003 have been fully considered but they are not

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persuasive. The rejection is maintained.

Summary

4. No claims are allowable.

5. Any inquiries concerning this communication or earlier communications from the

examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The

examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-

6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be

directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile

transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the

notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung 5. 7
January 6, 2004

ÝJEFFREY SIEW PRIMARY EXAMINEF

1/4/04